

section, meet standards of radiological quality as follows:

(A) The bottled water shall not contain a combined radium-226 and radium-228 activity in excess of 5 picocuries per liter of water.

(B) The bottled water shall not contain a gross alpha particle activity (including radium-226, but excluding radon and uranium) in excess of 15 picocuries per liter of water.

(C) The bottled water shall not contain beta particle and photon radioactivity from manmade radionuclides in excess of that which would produce an annual dose equivalent to the total body or any internal organ of 4 millirems per year calculated on the basis of an intake of 2 liters of the water per day. If two or more beta or photon-emitting radionuclides are present, the sum of their annual dose equivalent to the total body or to any internal organ shall not exceed 4 millirems per year.

(ii) Analyses conducted to determine compliance with paragraph (b)(5)(i) of this section shall be made in accordance with the methods described in the applicable sections of "Standard Methods for the Examination of Water and Wastewater," 15th Ed. (1980), and "Interim Radiochemical Methodology for Drinking Water," U.S. EPA, EMSL, EPA-600/4-75-008 (Revised), March 1976, both of which are incorporated by reference. The availability of these incorporations by reference is given in paragraph (b)(2) of this section.

(c) *Label statements.* When the microbiological, physical, chemical, or radiological quality of bottled water is below that prescribed by paragraphs (b)(2) through (b)(5), of this section, the label shall bear the statement of substandard quality specified in §130.14(a) of this chapter except that, as appropriate, instead of or in addition to the statement specified in §130.14(a) the following statement(s) shall be used:

(1) "Contains Excessive Bacteria" if the bottled water fails to meet the requirements of paragraph (b)(2) of this section.

(2) "Excessively Turbid", "Abnormal Color", and/or "Abnormal Odor" if the bottled water fails to meet the requirements of paragraph (b)(3) (i), (ii), or (iii), respectively, of this section.

(3) "Contains Excessive \_\_\_\_\_," with the blank filled in with the name of the chemical for which a maximum contaminant level in paragraph (b)(4) of this section is exceeded (e.g., "Contains Excessive Arsenic," "Contains Excessive Trihalomethanes") except that "Contains Excessive Chemical Substances" may be used if the bottled water is not mineral water.

(4) "Excessively Radioactive" if the bottled water fails to meet the requirements of paragraph (b)(5) of this section.

(d) *Adulteration.* Bottled water containing a substance at a level considered injurious to health under section 402(a)(1) of the act is deemed to be adulterated, regardless of whether or not the water bears a label statement of substandard quality prescribed by paragraph (c) of this section.

[60 FR 57124, Nov. 13, 1995; 60 FR 66495, Dec. 22, 1995, as amended at 61 FR 13264, Mar. 26, 1996; 61 FR 14480, Apr. 2, 1996; 63 FR 25769, May 11, 1998; 66 FR 16865, Mar. 28, 2001; 66 FR 17359, Mar. 30, 2001; 66 FR 35373, July 5, 2001; 66 FR 56035, Nov. 6, 2001]

## PART 166—MARGARINE

### Subpart A—General Provisions

Sec.

166.40 Labeling of margarine.

### Subpart B—Requirements for Specific Standardized Margarine

166.110 Margarine.

AUTHORITY: 21 U.S.C. 321, 341, 343, 347, 348, 371, 379e.

### Subpart A—General Provisions

#### § 166.40 Labeling of margarine.

The Federal Food, Drug, and Cosmetic Act was amended by Pub. L. 459, 81st Congress (64 Stat. 20) on colored oleomargarine or margarine by adding thereto a new section numbered 407. Among other things, this section requires that there appear on the label of the package the word "oleomargarine" or "margarine" in type or lettering at least as large as any other type or lettering on the label, and a full and accurate statement of all the ingredients contained in such oleomargarine or

margarine. It provides that these requirements “shall be in addition to and not in lieu of any of the other requirements of this Act”.

(a) Under section 403(g) of the Federal Food, Drug, and Cosmetic Act, any article that is represented as or purports to be oleomargarine or margarine must conform to the definition and standard of identity for oleomargarine or margarine promulgated under section 401 of the act (Subpart B of this part), and its label must bear the name “oleomargarine” or “margarine”.

(b) The identity standard for oleomargarine or margarine applies to both the uncolored and the colored article.

(c) In considering the requirement that the word “oleomargarine” or “margarine” be in type or lettering at least as large as any other type or lettering on the label, it must be borne in mind that at least three factors are involved—the height of each letter, the area occupied by each letter as measured by a closely fitting rectangle drawn around it, and the boldness of letters or breadth of the lines forming the letters. The type or lettering used should meet the following tests:

(1) The height of each letter in the word “oleomargarine” or “margarine” should equal or exceed the height of any other letter elsewhere on the label.

(2) The area of the closely fitting rectangle with respect to any of the letters in the word “oleomargarine” or “margarine” should equal or exceed the area of such rectangle applied to the same or a corresponding letter elsewhere on the label.

(3) The letters in the word “oleomargarine” or “margarine” should be equal to or exceed in prominence and boldness, such as breadth of lines forming the letters, the same or corresponding letters elsewhere on the label.

(d) [Reserved]

(e) The word “oleomargarine” or “margarine” (and thus the other information called for by the statute) should appear on each panel of the package label that might reasonably be selected by the grocer for display purposes at the point of sale.

(f) The amendment covering colored oleomargarine or colored margarine states that, “for the purposes of \* \* \*

section 407 of the Federal Food, Drug, and Cosmetic Act, as amended, the term ‘oleomargarine’ or ‘margarine’ includes: (1) All substances, mixtures, and compounds known as oleomargarine or margarine; (2) all substances, mixtures, and compounds which have a consistency similar to that of butter and which contain any edible oils or fats other than milk fat if made in imitation or semblance of butter”. Notwithstanding the difference between this definition and the definition and standard of identity for oleomargarine or margarine promulgated under section 401 of the act, it was the clear intent of Congress that any article which is represented as or purports to be oleomargarine or margarine is misbranded if it fails to comply with the definition and standard of identity for oleomargarine or margarine even though it may meet the statutory definition.

(g) Section 407(a) states that “Colored oleomargarine or colored margarine which is sold in the same State or Territory in which it is produced shall be subject in the same manner and to the same extent to the provisions of this act as if it had been introduced in interstate commerce”.

(h) Section 407(b)(4) requires that each part of the contents of the package be “contained in a wrapper which bears the word ‘oleomargarine’ or ‘margarine’ in type or lettering not smaller than 20-point type”. The Food and Drug Administration interprets this to mean that the height of the actual letters is no less than 20 points, or 20/72 of 1 inch.

(i) The wrappers on the subdivisions of oleomargarine or margarine contained within the package sold at retail are labels within the meaning of section 201(k) and shall contain all of the label information required by sections 403 and 407 of the Federal Food, Drug, and Cosmetic Act, just as in the case of 1-pound cartons, except that wrappers on the subdivisions contained within the retail package shall be exempt from compliance with the requirements of section 403 (e)(1), (g)(2), (i)(2), and (k) of the act with respect to the requirements for label declaration of the name and place of business of

the manufacturer, packer, or distributor and label declaration of ingredients when (1) the subdivisions are securely enclosed within and are not intended to be separated from the retail package under conditions of retail sale; (2) the wrappers on the subdivisions are labeled with the statement "This Unit Not Labeled For Retail Sale" in type size not less than one-sixteenth inch in height. The word "Individual" may be used in lieu of or immediately preceding the word "Retail" in the statement.

[42 FR 14477, Mar. 15, 1977, as amended at 46 FR 31005, June 12, 1981; 47 FR 32421, July 27, 1982]

### Subpart B—Requirements for Specific Standardized Margarine

#### § 166.110 Margarine.

(a) *Description.* Margarine (or oleo-margarine) is the food in plastic form or liquid emulsion, containing not less than 80 percent fat determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), section 16.206, "Indirect Method," under the heading "Fat (47)—Official Final Action," which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. Margarine contains only safe and suitable ingredients, as defined in § 130.3(d) of this chapter. It is produced from one or more of the optional ingredients in paragraph (a)(1) of this section, and one or more of the optional ingredients in paragraph (a)(2) of this section, to which may be added one or more of the optional ingredients in paragraph (b) of this section. Margarine contains vitamin A as provided for in paragraph (a)(3) of this section.

(1) Edible fats and/or oils, or mixtures of these, whose origin is vegetable or rendered animal carcass fats, or any form of oil from a marine species that has been affirmed as GRAS or listed as a food additive for this use, any or all of which may have been sub-

jected to an accepted process of physico-chemical modification. They may contain small amounts of other lipids, such as phosphatides or unsaponifiable constituents, and of free fatty acids naturally present in the fat or oil.

(2) One or more of the following aqueous phase ingredients:

(i) Water and/or milk and/or milk products.

(ii) Suitable edible protein including, but not limited to, the liquid, condensed, or dry form of whey, whey modified by the reduction of lactose and/or minerals, nonlactose containing whey components, albumin, casein, caseinate, vegetable proteins, or soy protein isolate, in amounts not greater than reasonably required to accomplish the desired effect.

(iii) Any mixture of two or more of the articles named under paragraphs (a)(2) (i) and (ii) of this section.

(iv) The ingredients in paragraphs (a)(2) (i), (ii), and (iii) of this section shall be pasteurized and then may be subjected to the action of harmless bacterial starters. One or more of the articles designated in paragraphs (a)(2) (i), (ii), and (iii) of this section is intimately mixed with the edible fat and/or ingredients to form a solidified or liquid emulsion.

(3) Vitamin A in such quantity that the finished margarine contains not less than 15,000 international units per pound.

(b) *Optional ingredients.* (1) Vitamin D in such quantity that the finished oleo-margarine contains not less than 1,500 international units of vitamin D per pound.

(2) Salt (sodium chloride); potassium chloride for dietary margarine or oleo-margarine.

(3) Nutritive carbohydrate sweeteners.

(4) Emulsifiers.

(5) Preservatives including but not limited to the following within these maximum amounts in percent by weight of the finished food: Sorbic acid, benzoic acid and their sodium, potassium, and calcium salts, individually, 0.1 percent, or in combination, 0.2 percent, expressed as the acids; calcium disodium EDTA, 0.0075 percent; propyl, octyl, and dodecyl gallates,